

**SPL OTC Sub-team
Question & Answer Document**

| Question or Comment | Please visit the respective Wiki page to view the Discussions/Responses |
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| Should we address anything related to the proposed rule such as “requiring the appropriate NDC on the drug label”? | |
| Clarify that the requirement for a foreign establishment to identify the name of all importers means the “importer of record”. What is the intent of this requirement? | |
| If within an NDA there is a formulation that has different flavors, can a company enter one Content of Labeling (CoL) SPL submission with the inactive ingredients for each of the flavors or does each flavor have to have its own CoL SPL submission? | |
| How can companies identify potential software vendors and suppliers? | |
| Does FDA have any technical information regarding configuration of subheadings in drug facts labeling (DFL) related to the LOINC codes? | |
| Can one DUNs number be associated with multiple labeler codes? | |
| What would be considered a source drug for an OTC? | |
| What is a reference drug? | |
| Why would we disclose confidential information in the drug listing if FDA may decide to make it public? | |
| What are the requirements for submitting the principal display panel (PDP) in SPL? Are companies required/expected to do an SPL update each time the PDP changes or is it acceptable to <i>not</i> list interim changes? | |
| How will the Jpeg images be handled within SPL? | |
| What constitutes a “representative” label? | |

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| How soon after submission of the Xform will FDA be posting the NLM-Daily website and is it necessary to proofread/confirm the version that is placed on the Daily Med site? | |
| How will FDA be collecting fees for the Registration Establishment forms? | |
| Are foreign companies who submit drug listings directly to the US FDA aware of the new draft guidance and that they need to submit forms in SPL formats? | |

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